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09/068,293	05/06/1998	ZIV SANDALON	AEM96-01A	2169

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[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

1636

DATE MAILED: 04/09/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/068,293

Applicant(s)

Sandalon et al.

Examiner

William Sandals

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Dec 16, 2002

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 1, 2, 4-13, 16-20, 22-37, 41-43, and 45-47 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1, 2, 4-13, 16-20, 22-37, 41-43, and 45-47 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on Dec 16, 2002 is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

*Cole Gay  
Att#28*

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on October 22, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/068,293 is acceptable and a CPA has been established. An action on the CPA follows.

### ***Status of the Claims***

2. Claims 1, 2, 4-13, 16-20, 22-37, 41-43 and 45-47 are pending in the application. Claims 1, 2, 4-13, 16-18, 20, 22-35, 37, 41-43 and 47 have been amended in Paper No. 24, filed December 16, 2002.

3. Amendments to the claims in Paper No. 24 have overcome the rejection of the claims 1, 2, 4-13, 16-20, 22-28 and 43 under 35 USC 112 second paragraph in the previous office action, and the rejection is withdrawn.

4. Amendments to the claims in Paper No. 24 have overcome the rejection of the claims 1, 2, 4 and 5 under 35 USC 102 (b) over Colomar et al., in the previous office action, and the rejection is withdrawn.

5. Amendments to the claims in Paper No. 24 have overcome the rejection of the claims 1, 2, 4-13, 16-20, 22-37, 41-43 and 45-47 under 35 USC 103 over Colomar et al. in view of

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Christensen et al., Carswell et al., Oppenheim et al. (J. Virol. Vol. 66, 1992) and US Pat No. 5,863,541, in the previous office action, and the rejection is withdrawn.

6. New grounds of rejection are presented below.

*Drawings*

7. The proposed drawing correction and/or the proposed substitute sheets of drawings, filed on December 16, 2002 have been approved. A proper drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The correction to the drawings will not be held in abeyance.

*Claim Rejections - 35 USC § 112*

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 5 recites the capsid protein "VPS". Capsid protein "VPS" is not described in the originally filed claims or specification. Therefore, the amendment of claim 5 to add the limitation where the capsid protein may be "VPS" constitutes new matter.

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10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1, 2, 4-13, 19, 25, 27, 29-34, 36, 37 and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 1 recites the limitation "the infectivity" in lines 28 and 29. There is insufficient antecedent basis for this limitation in the claim.

13. Claim 1 recites the limitation "the packaged recombinant nucleic acid" in lines 28-29. There is insufficient antecedent basis for this limitation in the claim.

14. Claim 5 recites the limitation "in said cell" in line 4. There is insufficient antecedent basis for this limitation in the claim.

15. Claim 9 recites the limitation "in said mammalian cell" in line 6. There is insufficient antecedent basis for this limitation in the claim.

16. Claim 10 recites the limitation "in said cell" in lines 4 and 10, and "in said mammalian cell" in line 15. There is insufficient antecedent basis for this limitation in the claim.

17. Claim 12 recites the limitation "said constituent is an exogenous protein or peptide" in line 2. There is insufficient antecedent basis for this limitation in the claim.

18. Claim 12 recites the limitation "in said cell" in line 4. There is insufficient antecedent basis for this limitation in the claim.

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19. Claim 25 recites the limitation "in said cell" in line 4. There is insufficient antecedent basis for this limitation in the claim.

20. Claim 27 recites the limitation "said exogenous protein" in line 5. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 28 recites the limitation "in said cell" or "in said mammalian cell" in lines 5, 12 and 16. There is insufficient antecedent basis for this limitation in the claim.

22. Claim 29 recites the limitation "said purified exogenous protein" in lines 11-12. There is insufficient antecedent basis for this limitation in the claim.

23. Claim 30 recites the limitation "any non-packaged protein" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

24. Claim 36 recites the limitation "non packaged DNA" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

25. Claim 37 recites the limitation "the mixture" in line 3. There is insufficient antecedent basis for this limitation in the claim.

26. Claim 43 recites the limitation "purified exogenous protein or peptide" in line 4. There is insufficient antecedent basis for this limitation in the claim.

27. \* - Each of the instances of "in said cell" above, lacks antecedent basis because the cell of the base claim refers only to a cell which contains antisense nucleic acids. - \*

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***Claim Rejections - 35 USC § 102***

28. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

29. Claims 1, 2, 4-11, 13, 16-20, 22-28, 35-37, 41-43, 45 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 92/16638 (Hellwig et al.).

Hellwig et al. teach at the abstract, pages 6-8, 17-20, 24 (section II. E.) and 25-26 (section V), an infectious particle complex comprising purified SV40 VP1, VP2 and VP3 proteins and a purified recombinant nucleic acid constituent packaged therein, and a method for making the infectious particle complex (see especially page 6, lines 5-32). The infectious particle may be used to infect a mammalian cell. The particle may be treated with nuclease digestion (see especially page 2, lines 5-12 and page 5, lines 10-16). The nucleic acid may encode a protein, and may be expressed in the cell, or may be an antisense nucleic acid (DNA or RNA), or may encode an antisense nucleic acid (see especially page 17). The encoded protein may be expressed in the cell. The encoded protein may replace, compliment or correct a protein which is endogenous to the cell (see especially page 18, lines 1-6). The complex may be in a pharmaceutically acceptable carrier (see especially pages 17-20).

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***Claim Rejections - 35 USC § 103***

30. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

31. Claims 12, 29-34 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 92/16638 (Hellwig et al.) in view of Hong et al.

The claims are drawn to a method for the *in vitro* construction of SV40 viruses or pseudoviruses comprising a constituent, where the constituent comprises a purified exogenous peptide or protein. SV40 capsid proteins self assemble *in vitro* in a mixture including the purified exogenous peptide or protein, whereby the purified exogenous peptide or protein is encapsidated into the self assembled SV40 pseudovirus. The peptide or protein may replace, compliment or correct a protein which is endogenous to the cell.

Hellwig et al. teach the invention as described above in the rejection under 35 USC 102.

Hellwig et al. did not teach that a desired protein may be packaged into the virus or pseudovirus.

Hong et al. teach at the abstract, and conclusion, a method of encapsidating a non-capsid, non-viral protein in a viral pseudocapsid. The viral pseudocapsid is derived from phage T4, which forms an icosahedral capsid.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the infectious particle complex comprising purified SV40 VP1, VP2 and VP3 proteins and a purified recombinant nucleic acid constituent packaged therein, and a method for making the infectious particle complex of Hellwig et al. with the viral capsid used for protecting the exogenous protein of Hong et al. to produce the instant claimed invention because both Hellwig et al. and Hong et al. teach the packaging of non-viral nucleic acids in self assembled viral capsid proteins to form a virus or pseudovirus. One of ordinary skill in the art would have been motivated to modify the teachings of Hellwig et al. with the teachings of Hong et al. (at the abstract) for the expected benefit of packaging of non-viral nucleic acids as well as proteins in pseudovirus capsids which self-assemble to stabilize and protect the encapsidated non-viral nucleic acids and proteins for delivery to the cells of Hellwig et al. Further, a person of ordinary skill in the art would have had a reasonable expectation of success in the producing the instant claimed invention given the teachings of Hellwig et al. and Hong et al. who demonstrate packaging of non-viral nucleic acids as well as proteins in pseudovirus capsids which self-assemble to stabilize and protect the encapsidated non-viral nucleic acids and proteins for delivery to cells.

### *Conclusion*

32. Certain papers related to this application are *welcomed* to be submitted to Art Unit 1636 by facsimile transmission. The FAX numbers are (703) 308-4242 and 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61

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(November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by the applicant or applicant's representative, and the FAX receipt from your FAX machine is proof of delivery. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications should be directed to Dr. William Sandals whose telephone number is (703) 305-1982. The examiner normally can be reached Monday through Thursday from 8:30 AM to 7:00 PM, EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Tech Center customer service center at telephone number (703) 308-0198.

William Sandals, Ph.D.

Examiner

March 21, 2003

  
REMY YUCEL, PH.D  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600